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EXAMINER	
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ART UNIT	PAPER NUMBER
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1997
DATE MAILED:

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Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No. 08/319,411

Applicant(s) Nelson et al.

Examiner A. Marschel

Group Art Unit 1807

☒ Responsive to communication(s) filed on 6-15-95 (IDS)

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Proposed (19 sheets)

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 7-36 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 21, and 30 are vague and indefinite as to what is meant when "a" is 0 and R^{13} is a conjugate. Claims 7 and 21 are also unclear as to what is meant by limiting the sum of either $p + q$ or $r + s$ as being not more than 10 when each parameter can be no more than 5. Claim 10 is unclear as to whether "a" must be one. This is implied but written limitations are clear whereas implied limitations are confusing. Claim 12 is vague and indefinite as to what is being limited therein in that it appears to limit the A moieties to content that they must already have. Applicants may intend to limit the A group to containing a conjugate in one of the R groups but this is not what is therein cited. Claim 17 is similarly confusing in that the C and D moieties seem already to be limited to contain the listed R groups. Applicants may intend the conjugate to be present as a limitation in one of these R groups but this is not what the claim presently cites.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-10, 18-24, and 30-33 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Egholm et al. (ref. BU).

Egholm et al. (BU) disclose PNA monomers with aromatic conjugate attachments to various bases as shown on page 800 which reads on the instant claims. These monomers are incorporated into PNA polymers prior to removal of the base conjugate protective groups thus reading on the above PNA polymer claims. Lysine end conjugate practice is also disclosed in the reference.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-4 and 6 are rejected under 35 U.S.C. § 103(a) as

being unpatentable over Summerton et al. (P/N 5,166,315).

The invention is directed to PNA conjugates with a variety of linkage sites on the PNA of conjugate moieties such as a metal chelator that may be utilized in nucleic acid cleavage.

Summerton et al. (P/N 5,166,315) disclose a generic variety of PNA embodiments with several types of backbone types in the PNA polymer. Two of these backbone types are depicted in Figures 8C and 8E of the reference. These backbone types are included in instant claim 1 which sites amino groups in the backbone with a tethered nucleobase. The R₁ moieties of Summerton et al. (P/N 5,166,315) are nucleobases. Conjugate practice wherein an iron chelate is attached to an end of the PNA polymer is disclosed in the reference in column 28, lines 15-32. Summerton et al. (P/N 5,166,315) also discloses the attachment of signal moieties onto the PNA polymers in column 28, line 57, through column 29, line 3.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention because Summerton et al. (P/N 5,166,315) generically disclose a variety of PNA polymer backbone types including the type with backbone amino group attachment of nucleobases as well as conjugates with metal chelators and signal moieties attached to these PNAs thus resulting in the instantly claimed conjugate practice of the above listed instant claims as a specie of the generic disclosures of the reference. Species are deemed both motivated and suggested within a generic disclosure, if the features of the

species are clearly described as they are in Summerton et al. (P/N 5,166,315).

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 30-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, and 9 of copending application Serial No. 08/108,591. Although the conflicting claims are not identical, they are not patentably distinct from each other because the L groups of both the instant disclosure and 08/108,591 include reporters, chelators, intercalators, etc. that are also included as conjugates as instantly defined on page 15 of the specification, for example. These L group embodiments thus may be defined as conjugates either in the L group or if a monomeric residue is located at an end of the polymer this includes end conjugate practice. Thus, each monomeric residue in the claimed PNA polymer of both disclosures may be designated as conjugate practice or PNA monomers thus resulting in common

embodiments between the claims of both disclosures that supports this rejection.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-20 and 30-36 are provisionally rejected under 35 U.S.C. § 103(a) as being obvious over copending application Serial No. 08/108,591.

Copending application Serial No. 08/108,591 has a common

inventor, but not the same inventors, compared with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. § 102(e) if patented. This provisional rejection under 35 U.S.C. § 103(a) is based upon a presumption of future patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 C.F.R. § 1.132 that any unclaimed invention disclosed in the copending application was derived from the inventor of this application and is thus not the invention "by another", or by a showing of a date of invention prior to the effective U.S. filing date of the copending application under 37 C.F.R. § 1.131.

The disclosure is objected to because of the following informalities:

In the specification on page 16, line 24, the word "drrivatized" appears to be misspelled.

In claim 7, line 4, the word "ineteger" appears to be misspelled.

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

September 30, 1996

Arden H. Marschel
ARDEN H. MARSCHEL
PATENT EXAMINER
GROUP 1800